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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/821,694	03/28/2001	William Daniel Hillis	0450-0001	9199

23980 7590 11/05/2002

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EXAMINER

LU, FRANK WEI MIN

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 11/05/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/821,694

Applicant(s)

HILLIS, WILLIAM DANIEL

Examiner

Frank W Lu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-114 is/are pending in the application.
- 4a) Of the above claim(s) 3,4,16,17,26,32,33 and 40-114 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-15,18-25,27-31 and 34-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 March 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6,8,10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group I, claims 1-39, species 5 (1), species 6 (1), and species 7(1) in Paper No. 12 is acknowledged. The traversal is on the ground(s) that: (1) "the subject matter of the claims of Groups I and II is not so different as to warrant a restriction." because the search for Groups I and II are identical since "[T]he claims of Groups I and II are both identified as requiring a search under class 435, subclass 6 (inventions involving nucleic acids)."; (2) "the classification of the claims of Group III in class 435, subclass 94 is not proper" since "[C]laims 87 and 88 do not recited the use of an isomerase to achieve the methods claimed therein"; (3) " the subject matter of the claims of Groups I and III is not so different as to warrant a restriction." because the search for Groups I and II are identical; (4) the subject matter of the claims of Groups II and III is not so different as to warrant a restriction because the search for Groups II and III are identical

After carefully considered the above arguments, the examiner agreed to combine Groups IV, V, and VI together and now Groups I, II, III, IV, V, and VI in previous office action will be Groups I, II, III, and IV. However, the arguments have not been found persuasive toward the withdrawal of the restriction requirement nor persuasive toward the relaxation of same such that Groups I, II, and III will be examined together and Groups IV and V will be examined together. First, Group I is directed to a method which is required the hybridization of at least two oligonucleotides to a target nucleic acid while Group II is directed to a method which is required the hybridization of a plurality of oligonucleotides to a plurality of target nucleic acids. Since a

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plurality of oligonucleotides and a plurality of target nucleic acids can be different, these method will generate different final products. Although some searches for Groups I and II may be identical, the searches for Groups I and II are not coextensive since the method of Group I and the method in Group II generate different final products. Second, the examiner agreed with applicant "the classification of the claims of Group III in class 435, subclass 94 is not proper". Since the examiner misspelled "435" instead of "436" in previous office action, the corrected classification for Group III should be class 436, subclass 94. Furthermore, the searches for Group III is different from that of Group I since the method of Group III is directed to determine a nucleotide at a position of interest in an analyte nucleic acid sequence by contacting the analyte nucleic acid with a first and second probes in a solution while the method in Group I is directed to employing oligonucleotide probes to obtain information on a target nucleic acid analyte involving an oligonucleotide array. The different purposes in Groups I and III will lead to different searches. Third, as showed above, since Groups II and III have different classifications and Group II is directed to a method which is required the hybridization of a plurality of oligonucleotides to a plurality of target nucleic acids while Group III is directed to a method which is required the hybridization of two oligonucleotides to a target nucleic acid, the searches for Groups II and III will be different.

The requirement for Groups I, II, and III is still deemed proper and is therefore made FINAL.

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Sequence Rules Compliance

2. The sequence listing submitted on August 19, 2002 has complied with Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Claim Objections

3. Claim 1 is objected to because of the following informalities: "is capable" in line 8 should be "is capable of" .
4. Claim 14 is objected to because of the following informalities: "an label" should be "a label".
5. Claim 20 is objected to because of the following informalities: "an RNA" should be "a RNA".
6. Claim 21 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim because claim 1 can be used for genetic analysis. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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8. Claim 1, 2, 5-15, 18-25, 27-31, and 34-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 1 is rejected as vague and indefinite in view of the phrase “each oligonucleotide probe comprising a sequence segment complementary, or complementary except at a position corresponding to position of the target sequence” because it is unclear what is “a position corresponding to position of the target sequence in each oligonucleotide probe”. Does “a position corresponding to position of the target sequence in each oligonucleotide probe” mean a possible mismatch region in the target sequence segment after the formation of a hybridization complex between each oligonucleotide probe and the target sequence segment? Please clarify.

10. Claim 1 is rejected as vague and indefinite in view of the phrase “the position of each oligonucleotide probe corresponding to the probed position” because it is unclear what is “the position of each oligonucleotide probe corresponding to the probed position”. Does this phrase mean a possible mismatch region in each oligonucleotide after the formation of a hybridization complex between each oligonucleotide probe and the target sequence segment? Please clarify.

11. Claim 1 is rejected as vague and indefinite in view of the phrase “one nucleotide that may be present in the target sequence segment is not represented in any set” because the word “may” in this phrase represents a possibility and will not be considered as a limitation of the claim.

Please clarify.

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12. Claim 2 is rejected as vague and indefinite in view of the phrase “four nucleotide may be present in the target sequence segment” because the word “may” in this phrase represents a possibility and will not be considered as a limitation of the claim. Please clarify.

13. Claim 2 is rejected as vague and indefinite in view of the phrase “each oligonucleotide probe comprises, at the position corresponding to the probed position a nucleotide base pairing with two nucleotides” because it is unclear what it intended. It is unclear what is “the position corresponding to the probed position” in each oligonucleotide. Does “the position corresponding to the probed position” in each oligonucleotide mean a possible mismatch region in each oligonucleotide after the formation of a hybridization complex between each oligonucleotide probe and the target sequence segment? How a nucleotide base in “the position corresponding to the probed position” in each oligonucleotide can pair with two nucleotides. Please clarify.

14. Claim 5 recites the limitation “a null hybridizing sequence comprising a nucleic acid” in the claim. There is insufficient antecedent basis for this limitation in the claim since there is no null hybridizing sequence in claim 1.

15. Claim 5 recites the limitation “the nucleic acid sequence of interest” in the claim. There is insufficient antecedent basis for this limitation in the claim since there is no “the nucleic acid sequence of interest” in claim 1.

16. Claim 6 is rejected as vague and indefinite because there is insufficient antecedent basis for a sequencing method since there is no sequencing step in claim 1.

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17. Claim 5 recites the limitation “an array of oligonucleotide probe” in the claim. There is insufficient antecedent basis for this limitation in the claim since there is no “an array of oligonucleotide probe” in claims 1 and 6.

18. Claim 14 is rejected as vague and indefinite because it is unclear what mean a label intrinsic to the target sequence segment. Does this claims mean that detection of a target sequence segment hybridizing to an oligonucleotide probe is by detection of target signal? Please clarify.

19. Claim 18 is rejected as vague and indefinite because it is unclear what it intended since a polymerase enzyme does not polymerize the formation of nucleic acid sequence. Please clarify.

20. Claim 20 recites the limitation “wherein hybridized nucleic acids are amplified by an RNA replicase enzyme” in the claim. There is insufficient antecedent basis for this limitation in the claim since it has been known in the art that polymerase chain reaction use DNA polymerase and does not use RNA replicase enzyme.

21. Claim 23 recites the limitation “genomic DNA” in the claim. There is insufficient antecedent basis for this limitation in the claim since there is no genomic DNA in claims 1, 18, 19, and 21.

22. Claim 24 is rejected as vague and indefinite because it is unclear what means “genomic cDNA” since it was known in the art that genomic DNA is different from cDNA.

23. Claim 34 recites the limitation “the second label moiety” in the claim. There is insufficient antecedent basis for this limitation in the claim since there is no second label moiety in claims 1 and 18.

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24. Claim 37 is rejected as vague and indefinite because it is unclear what means increasing kinetics of hybridization. Please clarify.
25. Claim 38 recites the limitation "the electric potential" in the claim. There is insufficient antecedent basis for this limitation in the claim since there is no "the electric potential" in claims 1, 6, 7, 9, and 14.

Conclusion

26. No claim is allowed.
27. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

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Any inquiry of a general nature or relating to the status of this application should be directed to the patent Analyst of the Art Unit, Ms. Chantae Dessau, whose telephone number is (703) 605-1237.

Frank Lu
November 1, 2002



ETHAN C. WHISENANT
PRIMARY EXAMINER